

App. No. : 09/185,408
Filed : November 3, 1998

REMARKS

35 USC 112, 2nd paragraph, says that the claims must be definite. By this amendment, neither narrowing nor broadening, for the definition is taken from the patent specification, any question about the meaning of "human" is provided, because it is tied to a comparison with the bovine situation. Support for the amendment is found throughout the patent specification, for example, at 7, lines 8-24:

By "human" glycoprotein hormone is meant that the number of amino acid substitutions made in the wild-type sequence does not exceed one-half the number of amino acid differences at corresponding positions in the corresponding polypeptide hormones between human and another species. Thus, the modified polypeptide hormone would be considered more like the wild-type polypeptide hormone of the human than the corresponding polypeptide hormone from the non-human species from which the amino acid substitutions are derived, based on the amino acid coding sequence. For example, if there were a total of 20 amino acid differences at corresponding positions in corresponding glycoprotein hormones between a human glycoprotein and a bovine glycoprotein hormone, a "human" glycoprotein hormone would be a modified wild-type human hormone which contains 10 or fewer amino acid substitutions within its amino acid sequence which are homologous to the corresponding amino acids in the bovine amino acid sequence. More specifically, the thyroid stimulating hormone, as set forth in the Examples contained herein, would be considered "human" if 20 or more of the 40 total amino acid differences between the α - and β - subunits of the human and bovine homologs are homologous to the amino acid at the corresponding position in the human thyroid stimulating hormone.

By providing the meaning taken from the patent specification of "human" in the claims, the definiteness requirement of the Patent Statute is satisfied.

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CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

On this set of pages, the insertions are double underlined while the deletions are struck through.

81. (AMENDED) A modified human thyroid stimulating hormone (TSH), which differs from the wild-type human TSH, said modified human TSH comprising an α -subunit and a β -subunit, said α -subunit comprising at least three basic amino acids in the α -subunit at positions selected from the group consisting of positions 11, 13, 14, 16, 17, and 20, wherein by human is meant the number of amino acid substitutions in the wild-type sequence does not exceed one-half the number of amino acid differences at corresponding positions in the TSH subunits between human and bovine ~~and non-human~~ species.

106. (AMENDED) A modified human thyroid stimulating hormone (TSH), which differs from the wild-type human TSH, said modified human TSH comprising an α -subunit and a β -subunit, said α -subunit comprising a basic amino acid in the α -subunit in at least one position selected from the group consisting of positions 11, 13, 14, 16, 17, and 20, wherein by human is meant the number of amino acid substitutions in the wild-type sequence does not exceed one-half the number of amino acid differences at corresponding positions in the TSH subunits between human and bovine ~~and non-human~~ species.

132. (AMENDED) A modified human thyroid stimulating hormone (TSH), which differs from the wild-type human TSH, said modified human TSH comprising an α -subunit and a β -subunit, said β -subunit comprising a basic amino acid in the β -subunit in at least one position selected from the group consisting of positions 58, 63, and 69, wherein by human is meant the number of amino acid substitutions in the wild-type sequence does not exceed one-half the number of amino acid differences at corresponding positions in the TSH subunits between human and bovine ~~and non-human~~ species.